"Horn-shaped" deformity of the Occlutech®-PDA device: case report

Deformidad en "forma de claxon" del dispositivo Occlutech-PDA: reporte de un caso

Deformidade em "formato de chifre" do dispositivo Occlutech-PDA: relato de caso

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El desarrollo de nuevas tecnologías necesita del acompañamiento en el tiempo para garantizar su seguridad, efectividad, costo/beneficio, etc. Conforme se gana experiencia en el uso de nuevos dispositivos para el tratamiento de cardiopatías congénitas, las complicaciones o efectos adversos de los mismos son observados en el seguimiento a corto, mediano y largo plazo. En el caso presentado en este manuscrito, describimos la deformidad en "forma de claxon de bicicleta" de un dispositivo Occlutech-PDA® que ocurrió cuando se intentó su implante durante el cateterismo, este episodio es un evento adverso que no había sido descrito hasta ahora. La importancia de este tipo de comunicados es alertar a la comunidad médica científica y a los fabricantes para mejorar la calidad de estos nuevos dispositivos y ofrecer mayor seguridad en los procedimientos a los pacientes..

Conceptos clave:

The Occlutech ductal occluder is a relatively new device for which there have been some reports about its effectiveness, safety and a few of its complications, yet the deformities this device could present during its percutaneous implantation have not been issued. Complications related to new technologies such as the one mentioned must be communicated as soon as possible, since it can help manufacturers to improve their quality and give patients greater safety.

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Abstract:

Introduction: the deformation phenomenon of devices used for percutaneous closure in intracardiac defects has been reported, but not of devices for closure of patent ductus arteriosus. **Objective:** to report a case of deformation of a relatively new type of device for closure of patent ductus arteriosus. **Method:** we report the case of an adult patient with hypertensive patent ductus arteriosus and a balloon occlusion test positive, whose occlusion was attempted with an Occlutech®-PDA device. **Results:** when the device implantation was carried out it took the form of a "bicycle horn" instead of its usual form, which is a "champagne cork", reason why it was extracted prior to its release; some maneuvers were performed in order to verify its configuration and was inserted again, but when repositioning it suffered the deformation mentioned above so it was definitively removed. The procedure was performed with another device. **Conclusions:** to our knowledge, no deformations of the Occlutech-PDA device during its implantation have been published. Adverse events related to new technologies must be reported as it helps manufacturers to improve quality and provide greater safety to patients.

Keywords: ductus arteriosus/abnormalities; hypertension, pulmonary; heart disease/congenital; adult; complications.

Resumen:

Introducción: se han comunicado del fenómeno de deformación de dispositivos utilizados para el cierre percutáneo de defectos intracardíacos, pero no acerca de los dispositivos para el cierre del conducto arterioso persistente. O**bjetivo:** comunicar un caso de deformación de un relativamente nuevo tipo de dispositivo oclusor de conducto arterioso persistente. M**étodo:** comunicamos el caso de un paciente adulto con conducto arterioso persistente hipertensivo y prueba de oclusión con balón positiva, en quien se intentó ocluirle con un dispositivo Occlutech®-PDA. **Resultado:** al momento de la entrega, el dispositivo adoptó la "forma de claxon de bicicleta" en lugar de su forma habitual la cual es en forma de "corcho de champagne", motivo por el que fue retirado previo a su liberación; algunas maniobras fueron realizadas para verificar su configuración y luego fue reinsertado, pero al reposicionarle nuevamente presentó la configuración anómala mencionada anteriormente por lo que fue retirado de manera definitiva. El procedimiento fue realizado con otro dispositivo. **Conclusión:** hasta donde conocemos, no hay comunicados acerca de deformación del dispositivo Occlutech®-PDA durante su implante. Los eventos adversos relacionados a nuevas tecnologías deben ser comunicados ya que esto puede ayudar a los fabricantes a mejorar su calidad y proveer mayor seguridad a los pacientes.

Palabras Claves: canal arterial/anomalías; hipertensión pulmonar; cardiopatías/congénito; adulto; complicaciones.

Resumo:

Introdução: O fenômeno da deformação de dispositivos usados para fechamento percutâneo em defeitos intracardíacos tem sido relatado, mas não de dispositivos para fechamento do canal arterial patente.
Objetivo: relatar um caso de deformação de um tipo relativamente novo de dispositivo para fechamento de canal arterial persistente.
Método: relatamos o caso de um paciente adulto com persistência do canal arterial hipertensivo e teste de oclusão com balão positivo, cuja oclusão foi tentada com dispositivo Occlutech-PDA.
Resultado: aquando da realização do implante do dispositivo este assumiu a forma da "buzina de bicicleta" em vez da sua forma habitual, que é uma "rolha de champanhe", pelo que foi extraída antes do seu lançamento; algumas manobras foram realizadas para verificar sua configuração e foi inserido novamente, mas ao ser reposicionado sofreu a deformação mencionada acima e foi removido definitivamente. O procedimiento foi realizado com outro dispositivo.
Conclusões: até onde sabemos, não foram publicadas deformações do dispositivo Occlutech®-PDA durante seu implantação. Os eventos adversos relacionados às novas tecnologias devem ser relatados, pois auxiliam os fabricantes a melhorar a qualidade e proporcionam maior

Palavras-chave: canal arterial/anormalidades; hipertensão pulmonar; cardiopatias/congênito; adulto; complicações.

INTRODUCTION

To date, the ideal device for the closure of patent ductus arteriosus (PDA) does not exist due to the diversity of its morphologies and sizes[1]. The Occlutech® Duct Occluder (ODO) is a relatively new device on which there are some experiences[2-10]. Our objective is to communicate the deformity that an ODO device presented when it was delivered transcatheter.

METHOD

A case report about an adult with hypertensive patent ductus arteriosus will be presented, in whom the occlusion was attempted with an Occlutech®-PDA device.
Ethics: the principles of the Declaration of Helsinki were respected.

RESULT

A 21-year-old male patient receiving sildenafil, with pulmonary hypertension (mPAP: 51 mmHg, PVRI: 4.7 WU·m^2), patent foramen ovale and type "E" PDA whose aortic and pulmonary diameters measured 15 and 8 mm respectively, length 11 mm (Figure 1A, arrow), positive vasoreactivity and balloon occlusion tests, for which an anterograde occlusion was attempted with an ODO device (Occlutech International, Turkey) of 10/12 x 12 mm length and aortic retention disc 18 mm in diameter through a 7 Fr sheath, without resistance on delivery. During the positioning of the device, the retention disc adopted a rounded shape and its body remained elongated (Figure 1B, arrow) giving it an appearance similar to a bicycle horn (**Figure 1C**), instead of the usual morphology (**Figure 2A, arrow**) similar to the champagne cork (**Figure 2B**) or to a fungus (**Figure 2C**). Upon seeing this, the device was reintroduced into the sheath and a new attempt was made to position it, although it again adopted the bicycle horn-shape described. The device was extracted and checked for macroscopic damage, it was stretched manually to verify the conformation of the usual configuration, also the device was deployed submerged in warm physiological solution, keeping it for a minute and then it was disconnected from the release system; it was screwed back into the delivery cable to introduce it again through the sheath. When trying to position the device once more, it assumed the anomalous shape mentioned above, which is why was removed permanently.

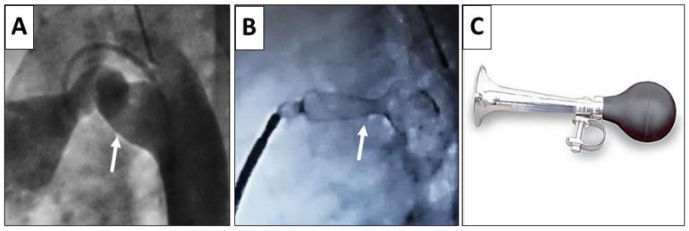

Fig. 1. A. Aortography: patent ductus arteriosus type "E" (arrow). **B.** Occlutech®-PDA device with horn-shaped deformity, positioned in the ductus arteriosus (arrow). **C.** Illustrative figure of horn.

The PDA was closed with another ODO device of the same size, leaving an angiographic shunt of moderate grade (**Figure 2A**). Hospital stay time: one day. medication: acetylsalicylic acid (ASA) at antiplatelet doses and sildenafil. Color Doppler echocardiogram: at 24 hours it showed mild residual shunt; in the first month without residual shunt or obstruction in the pulmonary artery or aorta; in the sixth month, the estimated pulmonary arterial systolic pressure (PASP) was 45 mmHg due to tricuspid regurgitation, so the medication was suspended. Follow-up time: one year, functional class (NYHA): 1, PASP remained at the same level.

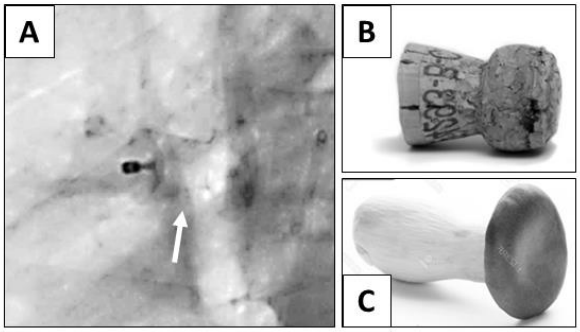

Figure 2. A. Usual form of the Occlutech®-PDA device in the shape of a "champagne cork" or a "mushroom" (arrow). **B.** Illustrative figure of champagne cork. **C.** Illustrative figure of mushroom.

DISCUSSION

The ODO is a self-expanding device that, according to its manufacturers, is designed to close PDA of various morphologies and has been successfully implanted even in hypertensive PDA[2-4,7-11], manufactured with nitinol wire coated with titanium oxide containing PTFE patch inside; marketed for approximately eight years by the Occlutech company whose factories are in Germany and Turkey, in our country the devices of Turkish origin are the ones that arrive[12].
Although type E PDA have a conical appearance, the particularity is their greater length and bizarre trajectory, which is why the ODO retention disc must be inserted into the aortic ampulla of the PDA so that the proximal (pulmonary) end of the device be anchored within the pulmonary artery. This can provoke the retention disc to increase the diameter of the PDA and favor an immediate residual shunting, as in our case. The size of the ODO chosen was only 2 mm larger than the minimum ductal diameter to avoid excessive oversizing of the device and cause alteration in its usual configuration when implanted[2,6].
There are reports on deformity of the Occlutech® Figulla Flex septal occluder (OFFSO) during its implantation but not on deformity of the ODO device, although problems have been reported with its release cable[3,8,12,13]. It has been proposed that OFFSO, made with the same material as ODO, may suffer deformity due to a decrease in the shape memory of the material caused by the small amount of metal it contains[13], but we are not convinced that this explanation is valid for ODO since deformations of other septal occluders made with nitinol have also been described[14].
Manufacturing failure, kinking or oversizing of the diameter of the delivery sheath, twisting of the nitinol wire, and the size of the retention disc device greater than 18 mm in diameter have been described as causes of septal occluder devices deformity[13,14].
When deformity of the device has occurred during its positioning, a maneuver that has been recommended in order to regain its original shape is to reintroduce the device into the sheath and reposition it. Nevertheless, because the ODO configuration is different from that of septal occluders, attempting to reconfigure the retention disc by pressing against the thin aortic wall is not recommended[14]. Once the device is removed, manual stretching can help to resolve the probable twisting of the nitinol wire meshwork that could occur during its passage through the delivery sheath. Immersing the device in warm liquid helps to check if it adopts the usual configuration, taking advantage of the "shape memory effect" nitinol has for medical use, thanks to the thermo-elastic property it possesses[14,15].

CONCLUSIONS

To our knowledge, there are no reports about the bicycle horn-shaped deformity of the ODO device during positioning. Being familiar with the typical shape of the device can prevent device migration due to misconfiguration while attempting to position it.

Conflict of Interest: No conflict of interest to disclose.

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Participation of the authors
Those who participated in the conception of the design, collection of information and preparation of the manuscript are publicly responsible for its content and approve its final version.

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